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10/532,033	08/09/2005	Jean-Pierre Vors	P/3610-57	6764

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EXAMINER	
ZAREK, PAUL E	
ART UNIT	PAPER NUMBER
4161	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,033	VORS ET AL.	
	Examiner	Art Unit	
	PAUL ZAREK	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-15 are currently pending. This is the first Office Action on the merits of the claim(s).

Priority

2. Applicant's claim for the benefit of a prior-filed international application, PCT/EP03/13335 (filed on 10/24/2003) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 10/24/2003.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on 04/21/2005. The foreign priority of the instant application is 10/24/2002.

Claim Objections

1. Claims 1-11 are objected to because of the following informalities: Claims should begin with an article. Independent claims should begin with --A--. Dependent claims should start with --The--. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd paragraph)

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 4, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claims 1, 4, and 6, are drawn to medicaments, which include the limitation “in particular.” This phrase is narrower than the statement of possible medicaments. Claim 3 recites the broad recitation R^2, R^3, R^4, R^5 are C_1-C_6 alkyl and R^6 is aryl, and the claim also recites R^2, R^3, R^4, R^5, and R^6 are preferably ethyl, methyl, methyl, methyl (linked to C_5 of benzyl ring M) and benzyl, respectively which is the narrower statement of the range/limitation. Claim 7 recites the broad recitation an antifungal medicament characterized by the mass ratio $0.02 \leq I/II \leq 50$, and the claim also recites an antifungal medicament characterized by the preferable mass ratio $0.1 \leq I/II \leq 20$, or more preferably $0.5 \leq I/II \leq 10$ which is the narrower statement of the range/limitation.

7. Claims 7 8, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 7 recites the limitation of "the mass ratio (I/II)." Claims 8, 9, and 11 recite the limitation "compound II" in the claims. There is insufficient antecedent basis for this limitation in the claim because the claims upon which they depend (Claims 1 or 4) are not limited by compound II.

9. Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 13 are drawn to a medicament (Claim 6) or a use of said medicament (Claim 13) wherein compound I is combined with compound II. Claims 6 and 13 limit compound II to a list of antifungal families, and then specific species of compound II are listed. It is unclear whether the claim limits compound II to one or more specific species (i.e. bifonazole or flucytosine), or one or more families (i.e. azoles or nucleoside analogues). Therefore, the rejected claims are indefinite.

10. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 12-15 provide for the use of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 12-15 are drawn to the use of the claimed medicament.

14. Claims 12-15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles, et al. (International Application WO 00/46184, 2000, provided in IDS).

17. Claims 1-4 are drawn to an antifungal medicament comprising at least one compound of formula I. Claims 1-3 limit the substituents of formula I. Claim 4 limits the medicament to one of 3 specific compounds.

Charles, et al., disclose an antifungal compound possessing the same number and identity of substituents claimed in the instant claims (pg 1, line 16 through pg 3, line 22). Preferred compounds disclosed in Charles, et al., (pg 3, line 24 through pg 4, line 14) correspond to the limitations of Claim 2. Especially preferred compounds of Charles, et al., correspond to the limitations of Claim 3, except that Charles, et al., "especially prefers" C_1-C_{10} alkyl, whereas Claim 3 is limited to C_1-C_6 alkyls. Compounds 364 and 365 (pg 46) correspond to N-ethyl-N-methyl-N'-[4-(4-chloro-3-trifluoromethylphenoxy)-2,5-dimethylphenyl]imidoformamide and N-ethyl-N-methyl-N'-[4-(4-fluoro-3-trifluoromethylphenoxy)-2,5-dimethylphenyl] imidoformamide, respectively, both of which are claimed in Claim 4. Therefore, Charles, et al., anticipate all the limitations of Claims 1-4.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charles, et al., in view of Bennett (Goodman & Gillman, The Pharmaceutical Basis of Therapeutics, 2001)

21. Claims 1 and 5-11 are drawn to an antifungal medicament comprising formula I (Claim 1) and at least one additional antifungal compound II (Claim 5). Claim 6 limits the antifungal compound II to known antifungal families. Claims 7 and 9-11 limit the medicament to specific mass ratios (Claims 7 and 9), having a synergistic effect with compound I (Claim 8), further comprising a pharmaceutically acceptable excipient (Claim 10), and having compounds I and II comprise from 0.5-99% of the medicament (Claim 11).

Charles, et al., teach an antifungal compound identical in scope to the compound of Claim 1. Charles, et al., do not teach combining compound I with another antifungal compound II, having a synergistic effect with a second compound, or further comprising a pharmaceutical excipient. Both compound I and compound II are known to have antifungal effects (Charles, et al. [abstract], and Bennett [entire chapter], respectively). Combining equivalents known for the same purpose is not a patentably distinguishing feature (MPEP §2173.05). "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Optimizing the mass ratio of compounds I and II or adjusting the composition such that compounds I and II

comprise 0.5-99% of the medicament is also not a patentably distinguishing feature (MPEP § 2144.05 II). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Finally, it is well known in the art to make medicaments comprising at least one excipient, which the FDA defines as substances other than the pharmacologically active drug or prodrug which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the teachings of Charles, et al., to incorporate the teachings of Bennett to combine compound I and compound II.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/589,011. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 5 of the instant application is drawn to a medicament comprising compound I with any second antifungal compound. Claim 1 of the '011 application is drawn to a composition comprising compound I and one of 43 specified antifungal compounds. The species disclosed in the '011 patent anticipate the genus of "antifungal compound" in the instant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/489,151. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 5 of the instant application is drawn to a medicament comprising compound I with any second antifungal compound. Claim 1 of the '151 application is drawn to a composition comprising compound I and an agriculturally acceptable antifungal compound. The species disclosed in the '151 patent anticipate the genus of "antifungal compound" in the instant.

25. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

26. No claims are allowed

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL ZAREK whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PATRICK NOLAN can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Ashwin Mehta/
Primary Examiner, Technology Center 1600